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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,481	07/07/2003	Michel Bublot	454313-2334.2	5144

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,481	BUBLOT ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-43* is/are pending in the application.

4a) Of the above claim(s) *28 and 31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-43* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I in the reply filed on 6/22/2006 is acknowledged. The traversal is on the ground(s) that (a) all four groups are directed to equine GM-CSF, (b) that the searches for the groups are overlapping, (c) that Inventions I and II are both related to equine GM-CSF proteins, and (d) that groups III and IV are indistinct. This is not found persuasive because: The four groups are *not* all directed to equine GM-CSF protein, but rather to protein, vaccines, and nucleic acids, as stated in the restriction requirement. It is understood that protein appears in both groups I and II; however, (i) claims 28-31 do not require protein, but can alternatively use nucleic acids, and would require substantial further search and consideration. For the time being, the method claims are not of the same scope as the composition claims, and the method and composition are patentably distinct for reasons of record in the previous communication. With regard to the searches being overlapping contrary to applicants' assertion that any search of the prior art in regard to group I will reveal whether any prior art exists as to the other Groups, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. With respect to distinctness of Inventions III and IV, such is moot, as neither was elected.

The requirement is still deemed proper and is therefore made FINAL.

The Examiner notes that, allowable subject matter having been found, if claims 28 and 31 were amended so as to be drawn to vaccines comprising an immunogen and the protein of SEQ ID NO: 9 or active fragment thereof, that such claims would be examined; it is noted that the art of record recognizes the use of GM-CSF as an adjuvant.

Information Disclosure Statement

The remainder of the information disclosure statement filed 11/30/04 has been considered and is enclosed herewith.

Specification

The abstract of the disclosure is objected to because it should be a single paragraph. It currently is a single paragraph followed by "Figure 1.", which should be deleted. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The continuing information at the first paragraph of the specification should be updated. 09/589460 issued as U.S. Patent No. 6,645,740 on 11/11/2003.

Appropriate correction is required.

Claim Objections

Claims 22 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. the limitations of the claim are drawn to DNA, and do not impart any further limitation on the claimed protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite for reciting "equine GM-CSF". According to the definition in the specification, such encompasses all functional equivalents. Specifically, the specification states that all proteins of any size that have "biological activity...substantially equivalent to that of the natural equine GM-CSF protein in horses and their species-specificity is not modified." (See U.S. Patent No. 6,645,740 at col. 2 lines 36-48.) Further, at column 2 line12 of the patent, it is stated that "DNA sequences having an homology equal or greater than 90%"..."with SEQ ID NO: 8, are equivalent sequences", and then at line 46 of the same column it is stated that "Are encompassed as equivalents any of the amino acid sequences encoded by any of the equivalent nucleotide sequences as defined above." Given the statements quoted herein, the metes and bounds of what constitutes "equine GM-CSF" cannot be determined; it is not clear what activity must be retained, what the metes and bounds of "substantially equivalent" activity are, nor what "species specificity" is intended, as there is no information on cross-species activity in the specification as originally filed.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 22, 24-27, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for horse FM-CSF of SEQ ID NO: 9 or biologically active fragments thereof, does not reasonably provide enablement for the full scope of any protein that meets the aforementioned specification definitions of being "equine GM-CSF", including all possible functional equivalents thereof. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is equine GM-CSF. According to the specification, equine GM-CSF is defined as encompassing all functional equivalents that "substantially" maintain activity and species specificity. The state of the prior art is that while GM-CSF was known from other species, including human and mouse, that the horse protein had not yet been isolated. While relative skill in the art is high as drawn to making muteins, the level of predictability is low with respect to predicting what properties those muteins will have. The specification contains no information as to species specificity, i.e. whether or not the isolated equine GM-CSF has activity in other animals, nor whether GM-CSF from other animals has activity in horses. Based upon a cursory review of the internet, the Examiner notes that human GM-CSF *has* been found to be active on equine dendiritic cells, see S.A. Hammond et al., "Functional characterization of equine dendriti cells propagated ex vivo using recombinant human GM-CSF and recombinant equine IL-4", Vet. Immunol. and Immunopath. 71:197-214, 1999. hence it seems apparent that there is cross-species reactivity. These factors lead to the conclusion above that the breadth of the claims is indefinite, and further lead to the conclusion that since the breadth cannot be determined, there is insufficient guidance as to how to make species within the metes and bounds of the claims. The only working example in the specification is of a single species, the protein of SEQ ID NO: 9. There are no working examples in which any muteins of any kind were made or tested for activity. There is no guidance as to how to alter SEQ ID NO: 9 to obtain proteins meeting the limitations of the claims. In view of the uncertain breadth of the claims, the lack of guidance as to how to make species in a manner commensurate in scope with the claims, and the lack of

working examples, it is concluded that it would require undue experimentation to practice the claimed invention in a manner commensurate in scope with the claims.

Claims 20, 22, 24-27, 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above, although indefinite, the claims are very broad, reading on all functional equivalents of equine GM-CSF, or variants with 90%, 92% or 95% identity to a protein encoded by the DNA of SEQ ID NO: 8, and compositions and methods of using same. The specification merely describes a single protein, SEQ ID NO: 9, and gives no guidance or working examples of variants that would be expected to meet the metes and bounds of the claims. The claims read on innumerable species, with only a single species, that of SEQ ID NO: 9, described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The protein or sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 9, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

WO 94/01133, cited by applicants, discloses the use of GM-CSF as an adjuvant. The publication does not disclose equine GM-CSF.

U.S. Patent Number 5,980,911, cited by applicants, discloses the use of GM-CSF as an adjuvant, and states that such may originate from a horse (see col. 3, lines 43-46), however there is no disclosure of nucleic acids encoding horse GM-CSF, nor of isolation of horse GM-CSF.

U.S. Patent Number 5,162,111, cited by applicants, discloses nucleic acids encoding human and murine GM-CSF.

Allowable Subject Matter

Claims limited in scope to horse GM-CSF are allowable over the prior art. It is noted that horse GM-CSF is 84.5% identical to ovine, 83.4% to red deer, 83.3% to goat, 77.3% to pig, and 77.21% to human (see enclosed search results, headed "us-10-614-481-9.rup"). Amendments to the claims should limit the GM-CSF in question to a reasonable scope that is supported by the specification with respect to both written description and enablement, under 35 U.S.C. §112, first paragraph.

Conclusion

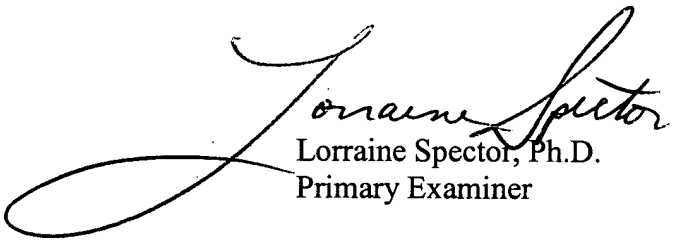
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner